



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1707]

Teva Pharmaceuticals USA, Inc., et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications for Pemoline Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the approval of five abbreviated new drug applications (ANDAs) for products containing pemoline. The holders of the applications requested withdrawal of the applications and have waived their opportunity for a hearing.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137.

SUPPLEMENTARY INFORMATION: FDA approved the following ANDAs for pemoline tablets for the conditions of use in the labeling of new drug application (NDA) 016832, the reference listed drug on which these ANDAs relied:

- ANDA 075030 approved on January 29, 1999
- ANDA 075287 approved on September 18, 2000
- ANDA 075595 approved on February 28, 2000

FDA approved the following ANDAs for pemoline chewable tablets for the conditions of use in the labeling of NDA 017703, the reference listed drug on which these ANDAs relied:

- ANDA 075555 approved on February 18, 2000
- ANDA 075678 approved on July 26, 2000

On October 24, 2005, FDA issued a *Postmarket Drug Safety Information for Healthcare Professionals* communication stating its conclusion that the overall liver toxicity risk of CYLERT (NDAs 016832 and 017703) and generic pemoline products outweighed the benefits of these products (<https://wayback.archive-it.org/7993/20171114124349/https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm126461.htm>). The applicants and other holders of approved applications for pemoline products ceased marketing the products at that time.

On August 10, 2018, the applicants listed in the table below requested that FDA withdraw approval of the pemoline ANDAs listed in the table under § 314.150(d) (21 CFR 314.150(d)), and, in doing so, waived their opportunity for a hearing. For the reasons discussed above, which the applicants do not dispute in their withdrawal request letters, and pursuant to the applicants' requests, FDA is withdrawing approval of the ANDAs listed in the table, and all amendments and supplements thereto, under § 314.150(d). Tablet strengths listed in the table below include all strengths FDA has identified as being previously approved under these ANDAs. In each case, approval of the entire application is withdrawn, including any strengths inadvertently missing from the table. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d), respectively).

| Application No. | Drug | Applicant |
|-----------------|--|--|
| ANDA 075030 | Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg | Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham PA 19044 |
| ANDA 075287 | Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg | Watson Laboratories, Inc., 425 Privet Rd., Horsham PA 19044 |
| ANDA 075555 | Pemoline Chewable Tablets, 37.5 mg | Teva Pharmaceuticals USA, Inc. |
| ANDA 075595 | Pemoline Tablets, 18.75 mg, 37.5 mg, and 75 mg | Actavis Elizabeth LLC, 425 Privet Rd., Horsham PA 19044 |
| ANDA 075678 | Pemoline Chewable Tablets, 37.5 mg | Do. |

Dated: May 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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